Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Panadol 500 mg Film Coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 500 mg paracetamol.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

White, capsule shaped film coated tablets with convex edges and debossed with a "P" within a circle on one face and a '-' on both sides of the breakline on the other. The tablet can be divided into equal halves.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Panadol is a mild analgesic and antipyretic. The tablets are recommended for use in the short-term management of headaches, musculoskeletal disorders, menstrual pains, toothache and for symptoms of common colds and flu. Panadol may also be used in the symptomatic relief of mild to moderate pain associated with osteoarthritis, as diagnosed by a doctor.

4.2 Posology and method of administration

Panadol is for oral administration

Adults (including the elderly) and children aged 16 years and over:
One or two tablets up to four times daily as required.

Children aged 10-15 years:
One tablet up to four times daily as required.
Children should not be given Panadol 500mg Tablets for more than 3 days without consulting a doctor.

Not recommended for children under 10 years of age.
These doses should not be repeated more frequently than every 4 hours and not more than 4 doses should be given in any 24 hour period.

The lowest dose necessary to achieve efficacy should be used.

4.3 Contraindications

Hypersensitivity to paracetamol or any of the other constituents.

4.4 Special warnings and precautions for use

Contains paracetamol. Do not use with any other paracetamol-containing products. The concomitant use with other products containing paracetamol may lead to an overdose. Paracetamol overdose may cause liver failure which can lead to liver transplant or death.

Underlying liver disease increases the risk of paracetamol related liver damage. Patients who have been diagnosed with liver or kidney impairment must seek medical advice before taking this medication.

Cases of hepatic dysfunction/failure have been reported in patients with depleted glutathione levels, such as those who are severely malnourished, anorexic, have a low body mass index or are chronic heavy users of alcohol.

Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment and sepsis, or in patients with malnutrition and other sources of glutathione deficiency (e.g. chronic alcoholism) who were treated with paracetamol at therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, prompt discontinuation of paracetamol and close monitoring is recommended. The measurement of urinary 5-oxoproline may be useful to identify pyroglutamic acidosis as underlying cause of HAGMA in patients with multiple risk factors.

Do not exceed the stated dose.

If symptoms persist, consult your doctor. Prolonged use except under medical supervision may be harmful.
This product should only be used when clearly necessary. Keep out of the sight and reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by cholestyramine. The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding; occasional doses have no significant effect. Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis due to pyroglutamic acidosis, especially in patients with risks factors (see section 4.4)

4.6 Fertility, pregnancy and lactation

Pregnancy

A large amount of data on pregnant women indicate neither malformative, nor feto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

Lactation

Paracetamol is excreted in breast milk. However, the level of paracetamol present is not considered to be harmful. Available published data do not contraindicate breastfeeding.

4.7 Effects on ability to drive and use machines

No significant effect.

4.8 Undesirable effects

Events reported from extensive post-marketing experience at therapeutic/labelled dose and considered attributable are tabulated below by System Organ Class and frequency.
Frequencies are defined as: very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1,000, <1/100), rare (≥1/10,000, <1/1000), very rare (<1/10,000), not known (cannot be estimated from available data).
Adverse event frequencies have been estimated from spontaneous reports received through post marketing data.

Body System	**Undesirable Effect**	**Frequency**
Paracetamol		
Blood and lymphatic system disorders	Thrombocytopaenia	Very rare
Metabolism and nutrition disorders	High anion gap metabolic acidosis*	Not known
Immune System disorders	Anaphylaxis, Cutaneous hypersensitivity reactions, including, among others, skin rashes, angiodema, Stevens Johnson syndrome and Toxic Epidermal Necrolysis. Very rare cases of serious skin reactions	Very rare

Respiratory, thoracic and mediastinal disorders	Bronchospasm in patients sensitive to aspirin and other NSAIDs	Very rare
Hepatobiliary disorders	Hepatic dysfunction	Very rare

*Cases of high anion gap metabolic acidosis due to pyroglutamic acidosis have been observed in patients with risk factors using paracetamol (see section 4.4). Pyroglutamic acidosis may occur as a consequence of low glutathione levels in these patients.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, website: www.hpra.ie.

4.9 Overdose

Paracetamol overdose may cause liver failure which can lead to liver transplant or death. Acute pancreatitis has been observed, usually with hepatic dysfunction and liver toxicity.

There is a risk of poisoning with paracetamol particularly in elderly subjects, young children, patients with liver disease, cases of chronic alcoholism and in patients with chronic malnutrition. Overdosing may be fatal in these cases.

Symptoms generally appear within the first 24 hours and may comprise: nausea, vomiting, anorexia, pallor, and abdominal pain, or patients may be asymptomatic.

Overdose of paracetamol in a single administration in adults or in children can cause liver cell necrosis likely to induce complete and irreversible necrosis, resulting in hepatocellular insufficiency, metabolic acidosis and encephalopathy which may cause coma and death. Simultaneously, increased levels of hepatic transaminases (AST, ALT), lactate dehydrogenase and bilirubin are observed together with increased prothrombin levels that may appear 12 to 48 hours after administration. Liver damage is likely in adults who have taken more than the recommended amounts of paracetamol. It is considered that excess quantities of toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are ingested), become irreversibly bound to liver tissue.

Some patients may be at increased risk of liver damage from paracetamol toxicity.
Risk Factors include: If the patient;

- Is on long-term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes.
- Regularly consumes ethanol in excess of recommended amounts
- Is likely to be glutathione depleted e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia

Emergency Procedure:

Immediate transfer to hospital.

Blood sampling to determine initial paracetamol plasma concentration. In the case of a single acute overdose, paracetamol plasma concentration should be measured 4 hours post ingestion.

Administration of activated charcoal should be considered if >150mg/kg paracetamol has been taken within 1 hour.

The antidote N-acetylcysteine, should be administered as soon as possible in accordance with National treatment guidelines.

Symptomatic treatment should be implemented.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anilides.
ATC Code: N02B E01.

Paracetamol has analgesic and antipyretic actions.

5.2 Pharmacokinetic properties

Paracetamol is rapidly and almost completely absorbed from the gastro-intestinal tract.

Human pharmacokinetic data demonstrate that early absorption of paracetamol (fraction of dose over the first 60 minutes) is 32% greater from Panadol compared to standard paracetamol tablet ($p<0.0001$) and less between-subject and less within-subject variability ($p<0.0001$) in early absorption of paracetamol from Panadol compared to standard paracetamol tablets.

Human pharmacokinetic data demonstrate that maximum plasma concentration of paracetamol is reached at least 25% faster for Panadol compared to standard paracetamol tablets in fasted and fed states ($p <0.01$).

Total extent of absorption of paracetamol from Panadol is equivalent to that from standard paracetamol tablets.

Human scintigraphy data demonstate that Panadol generally start to disintegrate by 5 minutes post dose. Human pharmaconkinetic data demonstrate that paracetamol can generally be detected in plasma by 10 minutes.

Concentration in plasma reaches a peak in 30 - 60 minutes. Plasma protein binding is variable. Plasma half-life is 1 - 4 hours. Maximum plasma concentration of paracetamol is reached faster for Panadol compared to standard paracetamol tablet in fasted and fed states ($p < 0.01$).

Paracetamol is relatively uniformly distributed throughout most body fluids.

Excretion is almost exclusively renal, in the form of conjugated metabolites.

5.3 Preclinical safety data

Conventional studies using the currently accepted standards for the evaluation of toxicity to reproduction and development are not available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pregelatinised starch Calcium carbonate Alginic acid Crospovidone Povidone (K-25) Magnesium stearate
Colloidal anhydrous silica
Carnauba wax
Opadry white (YS-1-7003) containing:
Titanium dioxide (E171), Hypromellose, Macrogol, Polysorbate 80

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of container

Opaque or clear 250 or 300 micron poly vinyl chloride (PVC)/Aluminium foil blister strips or blister packs comprised of clear thermoformed polyethylene terephthalate (PET) film of 250 µm and CRSF polyethylene terephthalate (PET) lid of 30 µm, packed

into cardboard cartons containing 6, 12, 24, 48 or 96 tablets or perforated opaque PVC/Aluminium foil blister strips packed into cardboard wallets containing 12 tablets.

Polyethylene sachet pack of 2 tablets (6 tablets in carton).

HDPE bottle containing 100 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Haleon Ireland Limited
Clocherane
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X35 Y983
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Ireland

8 MARKETING AUTHORISATION NUMBER

PA0678/107/001

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Date of last renewal: 11th August 2011

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July 2025